sections of this part. For a combination drug product that does not have an established name, the labeling of the product states the statement of identity for each ingredient in the combination, as established in the statement of identity sections of this part.

(b) *Indications.* The labeling of the product states, under the heading ''Indications,'' the indication(s) for each ingredient in the combination, as established in the indications sections of this part.

(c) *Warnings.* The labeling of the product states, under the heading ''Warnings,'' the warning(s) for each ingredient in the combination, as established in the warnings sections of this part.

(d) *Directions.* The labeling of the product states, under the heading ''Directions,'' directions that conform to the directions established for each ingredient in the directions sections of this part. When the time intervals or age limitations for administration of the individual ingredients differ, the directions for the combination product may not exceed any maximum dosage limits established for the individual ingredients in the applicable OTC drug monograph.

§ 349.80 Professional labeling.

The labeling of any OTC ophthalmic demulcent drug product provided to health professionals (but not to the general public) may contain instructions for the use of these products in professional eye examinations (i.e. gonioscopy, electroretinography).

PART 350—ANTIPERSPIRANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

Subpart A—General Provisions

Subpart B—Active Ingredients

Subpart C—Labeling

Subpart D—Guidelines for Effectiveness Testing

AUTHORITY: 21 U.S.C. 321, 351, 352, 353, 355, 360, 371.

SOURCE: 68 FR 34291, June 9, 2003, unless otherwise noted.

Subpart A—General Provisions

§ 350.1 Scope.

(a) An over-the-counter antiperspirant drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each condition in this part and each general condition established in § 330.1 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 350.3 Definition.

As used in this part:

Antiperspirant. A drug product applied topically that reduces the production of perspiration (sweat) at that site.

Subpart B—Active Ingredients

§ 350.10 Antiperspirant active ingredients.

The active ingredient of the product consists of any of the following within the established concentration and dosage formulation. Where applicable, the ingredient must meet the aluminum to chloride, aluminum to zirconium, and aluminum plus zirconium to chloride atomic ratios described in the U.S. Pharmacopeia-National Formulary. The concentration of ingredients in paragraphs (b) through (j) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in an aerosol or nonaerosol dosage form. The concentration of ingredients in paragraphs (k) through (r) of this section is calculated on an anhydrous basis, omitting from the calculation any buffer component present in the compound, in a nonaerosol dosage form. The labeled declaration of

the percentage of the active ingredient should exclude any water, buffer components, or propellant.

(a) Aluminum chloride up to 15 percent, calculated on the hexahydrate form, in an aqueous solution nonaerosol dosage form.

(b) Aluminum chlorohydrate up to 25 percent.

(c) Aluminum chlorohydrex polyethylene glycol up to 25 percent.

(d) Aluminum chlorohydrex propylene glycol up to 25 percent.

(e) Aluminum dichlorohydrate up to 25 percent.

(f) Aluminum dichlorohydrex polyethylene glycol up to 25 percent.

(g) Aluminum dichlorohydrex propylene glycol up to 25 percent.

(h) Aluminum sesquichlorohydrate up to 25 percent.

(i) Aluminum sesquichlorohydrex polyethylene glycol up to 25 percent.

(j) Aluminum sesquichlorohydrex propylene glycol up to 25 percent.

(k) Aluminum zirconium octachlorohydrate up to 20 percent.

(l) Aluminum zirconium octachlorohydrex gly up to 20 percent.

(m) Aluminum zirconium pentachlorohydrate up to 20 percent.

(n) Aluminum zirconium pentachlorohydrex gly up to 20 percent.

(o) Aluminum zirconium tetrachlorohydrate up to 20 percent.

(p) Aluminum zirconium tetrachlorohydrex gly up to 20 percent.

(q) Aluminum zirconium trichlorohydrate up to 20 percent.

(r) Aluminum zirconium trichlorohydrex gly up to 20 percent.

Subpart C—Labeling

§ 350.50 Labeling of antiperspirant drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an ''antiperspirant.''

(b) *Indications.* The labeling of the product states, under the heading ''Uses,'' the phrase listed in paragraph (b)(1) of this section and may contain any additional phrases listed in paragraphs (b)(2) through (b)(5) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the uses that have been established and listed in paragraphs (b)(1) through (b)(5) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(1) For any product, the labeling states [select one of the following: ''decreases,'' ''lessens,'' or ''reduces''] ''underarm'' [select one of the following: ''dampness,'' ''perspiration,'' ''sweat,'' ''sweating,'' or ''wetness''].

(2) The labeling may state ''also [select one of the following: 'decreases,' 'lessens,' or 'reduces'] underarm [select one of the following: 'dampness,' 'perspiration,' 'sweat,' 'sweating,' or 'wetness'] due to stress''.

(3) For products that demonstrate standard effectiveness (20 percent sweat reduction) over a 24-hour period, the labeling may state [select one of the following: ''all day protection,'' ''lasts all day,'' ''lasts 24 hours,'' or ''24 hour protection''].

(4) For products that demonstrate extra effectiveness (30 percent sweat reduction), the labeling may state ''extra effective''.

(5) Products that demonstrate extra effectiveness (30 percent sweat reduction) sustained over a 24-hour period may state the claims in paragraphs (b)(3) and (b)(4) of this section either individually or combined, e.g., ''24 hour extra effective protection'', ''all day extra effective protection,'' ''extra effective protection lasts 24 hours,'' or ''extra effective protection lasts all day''.

(c) *Warnings.* The labeling of the product contains the following statements under the heading ''Warnings'':

(1) ''Do not use on broken skin''.

(2) ''Stop use if rash or irritation occurs''.

(3) ''Ask a doctor before use if you have kidney disease''.

(4) *For products in an aerosolized dosage form.* (i) ''When using this product